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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,185	09/07/2001	Franz-Josef Meyer-Almes	P66688US0	6405
136	7590	06/02/2004	EXAMINER	
JACOBSON HOLMAN PLLC 400 SEVENTH STREET N.W. SUITE 600 WASHINGTON, DC 20004			SAUCIER, SANDRA E	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/856,185	Applicant(s) MEYER-ALMES, FRANZ-JOSEF	
	Examiner Sandra Saucier	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-50 is/are pending in the application.
- 4a) Of the above claim(s) 50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/26/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 29–50 are pending. Claims 29–49 are under examination. Claim 50 is withdraw as being directed to a non-elected invention.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on 3/12/1999. Applicant has provided a copy of notice that PTO has received a certified copy of DE 19910995.9. However, the certified copy of DE 19910995.9 is not found with the present file. The examiner will send an inquiry to the PCT Office for a duplicate copy to be scanned into the present application in an effort to resolve this issue prior to allowance.

Election/Restrictions

Newly submitted claim 50 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The claim is a composition claim. No composition claims were present in the originally presented claims.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. The groups are:

Group I, claims 29–49, drawn to a method for determining the chemosensitivity of cells towards a substance.

Group II, claim 50, drawn to a composition comprising a cytostatic agent and a marker having a detectable interaction with PS.

A national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the of following combinations of categories;

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- (1) a product and a process specially adapted for the manufacture of said product; or
 - (2) a product and a process of use of said product; or
 - (3) a product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
 - (4) a process and an apparatus specifically designed for carrying out said process; or
 - (5) a product, a process specially adapted for the manufacture of the said product and an apparatus specifically designed for carrying out said process.
- 37 CFR 1.475.

The groups of invention fall within category (2), a product and a method of use of that product.

However, the inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Schutte *et al.* [U1] disclose a composition comprising a cytostatic agent and a marker having a detectable interaction with phosphatidylserine.

The expression "special technical feature" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art (PCT Rule 13.2). Thus, a feature found in the prior art cannot be considered to be a special technical feature.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 50 is withdrawn

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from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections – 35 USC § 102

Claims 29–49 are rejected under 35 U.S.C. 102(b) as being anticipated by Schutte *et al.* [U1].

The claims are directed to a method of detecting apoptosis induced by a substance in a sample comprising incubating the cells with the substance essentially concurrently with a PS marker and detecting the binding between the marker and PS as a function of time in the sample.

Schutte *et al.* disclose a method of measuring apoptosis induced by a substance (okadaic acid or roscovitine) comprising incubating the cells with the substance for a period of time and then adding annexin V-FITC to the medium and further incubating. It appears that no washing step is performed between the addition of the substance and the addition of annexin V-FITC; thus, the incubation of marker and substance is concurrent. (Page 65, figure legends). PI is also used as a measure of necrosis. Imaging is by confocal scanning laser microscopy or flow cytometry. Cells identified as apoptotic are standardized for the total number of cells (Fig. 3). Parallel cultures (controls) are also analyzed (page 66). The detection step is by flow cytometry or confocal scanning laser microscopy which are the same detection methods in the instant method; therefore, the time taken to perform the same methods may be reasonably assumed to be the same length of time. The Ca⁺⁺ concentration in DMEM/F12 is about 1 mM.

Response to Arguments

Applicant's arguments filed 3/26/04 have been fully considered but they are not persuasive.

Applicant argues that the instant claims are drawn to a “homogeneous method” as opposed to the “heterogeneous method” of the prior art.

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First, "homogeneous method" is not a term of art, and limitations in the specification are not read into the claim. Thus, very little patentable weight can be given to this limitation.

Applicant argues that Schutte *et al.* washes the cells twice with culture medium in order to remove excess marker. Although this appears to be correct, no limitation appears in the claims to prevent such a washing step.

Applicant then states that there is no concurrent incubation in Schutte *et al.* This is not correct as the annexin V-FITC and the roscovitine/okadaic acid are both in the culture medium AT THE SAME TIME. It is believed that this fulfills the claim limitation as this is a concurrent presence of the substance and the marker in the cell culture medium.

Applicant argues that Schutte *et al.* do not teach detection of the binding of PS and the marker as a function of time. Please look at Figure 3 of the reference where # apoptic cells are compared over time. This appears to be a detection of the binding of PS as a function of time.

Applicant argues that the instant method is superior to the prior art method. This may be true, but the method AS CLAIMED still appears to be anticipated by the prior art.

Conclusion

Applicant's amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

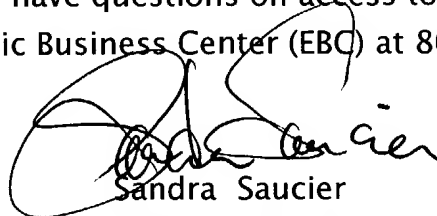
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the

advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday, Tuesday, Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Sandra Saucier', is written over a circular stamp. The signature is fluid and cursive.

Sandra Saucier
Primary Examiner
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